Attorney Ref. No: 1077-023-PWH

IN THE US PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: McEwen, J.

Application No: 09/886,327

For: *Matching Limb Protection Sleeve for Tourniquet Cuff*

Group Art Unit: 3731

Filed: Jun 21, 2001

Examiner: BUI, Vy, Q.

APPEAL BRIEF

(37 CFR § 41.37)

COMMISSIONER FOR PATENTS:

Sir:

This brief is in furtherance of the Notice of Appeal filed June 30, 2004, in connection with the captioned application. The $340 fee required under 37 CFR 41.20(2) is enclosed herewith.

CERTIFICATE OF TRANSMISSION/MAILING

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Patrick W. Hughey

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1. Real Party in Interest

The real party in interest is Western Clinical Engineering, Ltd., a British Columbia corporation.

2. Related Appeals and Interferences

No related appeals or interferences.

3. Status of Claims

Claims 1, 2, 5, 6, 8 – 13, 15 – 17, and 19 – 22 stand rejected and are the claims on appeal. Claims 3, 4, 7, 14, and 18 have been canceled.

4. Status of Amendments

No amendment has been filed subsequent to the office action of January 5, 2004, which twice rejected the claims on appeal here.

5. Summary of Claimed Subject Matter

The present invention concerns an apparatus and method for protecting a patient's limb from tourniquet related injury through use of properly matched components of a tourniquet system that includes a tourniquet cuff component and an underlying sleeve component.

The method and apparatus respectively recited in claims 1 and 6 can be carried out by selecting a tourniquet cuff component 6 to apply around the limb 4 of a surgical patient.[1] A particular cuff is selected from a number of cuffs, each cuff having a different length. Four such cuffs are shown at 6, 14, 16 and 18 in Fig. 2. As shown in a tabulation of differently sized cuffs,[2] each particular cuff has associated with it a recommended minimum patient-limb circumference and a recommended maximum limb circumference. That is, for a given patient's limb circumference, a corresponding tourniquet cuff is selected so that the patient's limb circumference is between the minimum and maximum recommended circumference for the selected cuff. The specification explains[3] how such

[1] Specification, page 7, line 24 – page 8, line 6.

[2] Specification, page 8.

[3] Specification, page 9, lines 16 – 27.

a properly selected (sized) tourniquet cuff will provide four desired conditions (such as uniform pressure application, etc) when applied to the limb of the patient.

A stretchable limb protection sleeve 2 is selected for use with the tourniquet cuff. The selected sleeve is placed around the limb so that it is under the applied cuff. One of several sleeves of differing sizes is selected for use with a cuff that is sized for use with limbs of a particular circumferential range, as just noted above.

In short, the sleeve size is selected to ensure that it is stretched when applied to a limb that has a circumference at the low end of the limb-circumference range for the selected cuff. This stretching eliminates wrinkles in the sleeve, and the stretched sleeve thus applies a slight pressure[4] to the limb. Also, when the selected sleeve is applied to a limb that is on the high end of the limb-circumference range, the pressure applied to the limb by the stretchable sleeve will remain low enough[5] to prevent interference with blood flow in the limb.[6] Put another way, the sleeve is designed to ensure that, when applied, it avoids wrinkles but does not interfere with blood flow, which is the function of the controlled tourniquet cuff.

As an aspect of the present invention, there is provided an effective way for users to readily match a properly sized cuff with the corresponding, properly sized sleeve and thus select and use these two components safely together. The subject matter defined in independent claims 1, 6, 13 and 15 calls for marking or otherwise providing indicia to show that the cuff and the sleeve components match one another. In one embodiment, visual indicia of the correspondence between sleeve and cuff include color coding, such that the color of the cuff tie straps 20, 22 (Fig. 1) is the same as the color of the edge 46 of the sleeve (Fig. 1).[7] The specification, on page 13 lines 4 – 11, lists several other means for matching cuff and sleeve (corresponding cuff/sleeve numbers, letters, etc) which correspond to the matching means elements of claims 6 and 13.

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[4] For example, about 2 mmHg.

[5] For example, less than 25 mmHg.

[6] Specification page 10, line 16 – page 11, line 2.

[7] Page 13, lines 2 – 3.

In one embodiment[8] the stretchable sleeve is described and claimed (for example, in claim 13) as having a width that is greater than the width of the cuff, thereby to enable part of the sleeve to completely underlie the cuff when the cuff is in the cylindrical configuration while another part of the sleeve is folded over the cuff.[9]

6. Grounds of Rejection to be Reviewed on Appeal

a. Claims 1, 5, 6, 11, and 13 – 15 stand rejected under 35 USC § 102(b) as being anticipated by or, in the alternative, rendered obvious under 35 USC § 103(a) in view of Smith & Nephew Richards.

b. Claims 2, 8 – 10, 12 and 16 – 17, and 19 - 22 stand rejected under 35 USC §103(a) as obvious in view of Smith & Nephew Richards.

7. Argument

a. The Rejection of Claims 1, 5, 6, 11, and 13 –15 Under 35 USC § 102(b) or 35 USC § 103(a) Should be Reversed.

Claims 1, 5, and 11

In rejecting claim 1 the Examiner points out that each Smith & Nephew Richards disposable cuff is color coded by size. That prior art reference also mentions that a stockinette sleeve, which is "standard on each tourniquet"[10] is applied in a way to avoid wrinkles in the sleeve of cuff.[11]

The Examiner then concludes that, as respects Smith & Nephew Richards:

"Inherently, there must be a means (such as a label, a mark, an alphabet code, a color code ...) to indicate a match between a cuff and an associated stockinette sleeve to help a physician to select a right pair of cuff and stockinette sleeve to use on a patient. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to mark or label a sleeve to match an associate cuff so as to help a physician or a user to identify the right pair of cuff and sleeve for a patient."[12]

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[8] Illustrated, for example in Fig. 6c.

[9] Page 15, lines 21 – 24.

[10] Last line of *Catalog Information*, page 2 of the Smith & Nephew Richards brochure.

[11] Step 4 of *Application* steps, page 1 of Smith & Nephew Richards brochure

[12] Page 3, lines 10 – 16 of Jan 5, 2004 Office action.

In response, appellant respectfully traverses the rationale set forth in the Office action for asserting that the claimed marking of a cuff *and* sleeve to show that those components match one another is an inherent part of Smith & Nephew Richards. Smith & Nephew Richards apparently packs together a cuff and a sleeve, and the associated guidelines warn the user to avoid any wrinkles in the sleeve. There is no rationale, however, for reading that reference to include markings on the sleeve that match markings on the cuff.

Appellant submits, therefore, that a proper inherency-based rejection has not been made as is required in the Manual of Patent Examining Procedure (MPEP), such as set forth in § 2112, a pertinent portion of which is quoted here:

> "*To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*'" *In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)*

As mentioned above, these claims were also rejected (in the alternative) as being obvious in view of Smith & Nephew Richards. In particular, the Office action concluded that it would be obvious for one of ordinary skill to mark or label a sleeve to match an associated cuff "*to help a physician or a user to identify the right pair of cuff and sleeve for a patient.*"

In reply, appellant notes that there is nothing in the Smith & Nephew Richards reference that suggests this marking. In this regard, appellant points out that apart from apparently recognizing that sleeve wrinkles are undesirable, there is nothing in Smith & Nephew Richards that suggests the necessity of also ensuring that a wrinkle-free sleeve is not too tight (that is, applying a pressure of, for example, more that 25 mmHg, which could lead to undetected interference with blood flow and consequent injury).

It is appellant's solution to this potential sleeve over-pressurization problem that leads to the claimed marking of a sleeve to match a cuff. Put another way, an unmarked sleeve may readily avoid the wrinkling problem of concern in Smith & Nephew Richards, but two different wrinkle-free sleeves may apply two different pressures to a limb (one of

which pressures may be injuriously high). Thus, each of the claimed sleeves requires a specific marking to ensure it is matched with a cuff that is used with a limb that is within a predetermined limb-circumference range, thereby ensuring that the limb will not be over-pressurized by the underlying sleeve.

Since Smith & Nephew Richards does not concern itself with a tight-sleeve-overpressure problem addressed in the present application, there is no suggestion or motivation there to match and mark the cuffs and sleeves to avoid applying too much pressure to the limb. Smith & Nephew Richards packages a sleeve with each cuff and asks the user to avoid wrinkles. There is nothing in the art of record to suggest that Smith & Nephew Richards be modified to also incorporate a marked sleeve that matches a similarly marked cuff.

As noted in the MPEP, a *prima facie* case of obviousness first requires that the prior art suggest the desirability of the claimed invention:

> *"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings....* " MPEP §2143

In the case at hand, there is nothing in the prior art that would suggest modifying Smith & Nephew Richards to include sleeves that are marked to match cuffs as presently claimed. Accordingly, appellant submits that a proper case of *prima facie* obviousness has not been made, and the rejections should be withdrawn.

Claim 6

Claim 6 is an apparatus claim that is generally analogous to method claim 1. The cuff recited here has a first indicium thereon that is indicative of the limb circumference range for that cuff. The claimed matching means for matching a proper sleeve --that is, one sized to apply pressure above a predetermined minimum amount (avoiding wrinkles) and below a predetermined maximum amount (avoiding interference with blood flow)-- includes a second indicium on the sleeve that corresponds to the first indicium on the cuff.

As set forth above in connection with claim 1, nothing in the Smith & Nephew Richards reference can be fairly characterized as disclosing as inherent, or obvious, a sleeve having an indicium that corresponds to another indicium on the cuff. Accordingly, appellant believes that neither a proper case of anticipation nor of *prima facie* obviousness has been made as respect claim 6, and the rejection of this claim should be withdrawn.

Claims 13 and 22

Nothing in Smith & Nephew Richards discloses or suggests any way of providing a visual indication of a size correspondence between the cuff and sleeve. Moreover, nowhere in that reference (or in the office action) is there a disclosure or suggestion that the sleeve "*has a width that is greater than the width of the cuff thereby to enable part of the sleeve to completely underlie the cuff when the cuff is in the cylindrical configuration while another part of the sleeve is folded over the cuff*" as recited in claim 13.

Accordingly, the rejection of claim 13 and dependent claim 22 should be reversed.

Claims 15 and 17

Method claim 15 includes the step of marking a selected sleeve[13] to show correlation with a particularly sized cuff. Nowhere in Smith & Nephew Richards is there shown or suggested the notion of marking a stretchable sleeve for any reason. Accordingly, appellant believes the rejection of these claims should also be withdrawn.

b. The Rejection of Claims 2, 8 – 10, 12 and 16 – 17, and 19 – 22 Under 35 USC §103(a) Should be Reversed.

Claims 2 and 12

Dependent method claim 2 specifies that the matching step of claim 1 comprises applying a selected color on the cuff and the same selected color on the sleeve. Dependent apparatus claim 12 points out that the first and second indicium recited in claim 6 are the same color.

[13] That is, selected to have a certain unstretched circumference measurement and limb pressure characteristics when applied to a limb.

The only reference (Smith & Nephew Richards) applied in rejecting this claim as obvious discloses a stockinette sleeve as standard with each of a variety of tourniquet cuffs, and instructions for applying the sleeve to avoid wrinkles. The Examiner acknowledges that Smith & Nephew Richards does not disclose such color coding, but concludes that:

> *"However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to mark both a cuff and an associate sleeve with the same color to help a user to identify and match quickly a separate cuff and its associate sleeve and avoid a use of a pair a cuff and a unmatched sleeve, which could render a tourniquet procedure less effective."*[14]

No secondary reference is applied for showing why one of ordinary skill would be motivated to modify the teachings of Smith & Nephew Richards in this way.[15] Accordingly, appellant believes that the analysis just quoted arises from the application of hindsight, with only the current claims to guide one to modify Smith & Nephew Richards to arrive at what is defined in claims 2 and 12. Accordingly, appellant submits that a proper case of *prima facie* obviousness of these claims has not been made and, therefore, the rejection should be reversed.

Claim 8

This claim specifies a dual layer, folded design for the sleeve wherein the edge of the sleeve away form the fold edge is sewn together. (Claim 9 points out that the second, matching indicium is incorporated into the sewn edge). No such construction is disclosed in the art of record, although the Examiner concluded that it would be obvious to make the sleeve in this fashion. Appellant respectfully submits that the rejection, as articulated in the final paragraph of page 4 of the Office action, does not provide the necessary indication of how the prior art suggests such a construction. Accordingly, this rejection is not a proper *prima facie* obviousness type, and should also be reversed.

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[14] Jan 5, 2005 Office action, page 4.

[15] Smith, US Pat No. 4,650,475, was not relied upon in rejecting the claims. This reference relates to the injection of pharmaceuticals, and is not analogous to the current invention.

Claim 9

Since no reference of record discloses or suggests incorporating a cuff/sleeve matching indicium in a sewn edge of a two-layer sleeve, this rejection should also be reversed.

Claim 10

This claim points out that the sleeve has a width that is greater than the width of the cuff, thereby to enable part of the sleeve to completely underlie the cuff while another part of the sleeve is folded over the cuff. The Office action does not point out where in the art of record the particulars of this sleeve sizing is taught or suggested. Accordingly, appellant submits that the lack of teaching or suggestion in the prior art renders this claim patentable, and the rejection should be reversed.

Claim 16

As noted above, the present invention relates in part to the understanding of what pressure is applied to a patient's limb by a stretchable sleeve.[16] As one aspect of the invention, a minimum sleeve-to-limb pressure is defined for removing wrinkles in an applied sleeve. This relatively low pressure may be about 2 mmHg as specified in claim 16. Since nothing in the Smith & Nephew Richards suggests measuring the pressure applied by the sleeve to the limb or selecting a sleeve to apply such a pressure at a minimum of about 2 mmHg, claim 16 is believed to be allowable over the art of record.

Claims 19 and 20

As another aspect of the invention, a maximum sleeve-to-limb pressure is defined that is less than a pressure for partially obstructing venous blood flow in the limb. Since nothing in the Smith & Nephew Richards suggests measuring the pressure applied by the sleeve to the limb or selecting a sleeve to apply a pressure at such a maximum level, claim 19 and dependent claim 20 are believed to be allowable over the art of record.

Claim 21

This claim adds to claims 19 and 1 a method step of measuring the pressure applied by the sleeve to the limb for establishing the predetermined maximum pressure

[16] The sleeve underlies the tourniquet cuff itself. The cuff applies (controlled) pressure to the limb during a surgical procedure.

applied by the sleeve to the limb. Nothing in the Smith & Nephew Richards suggests measuring the pressure applied by the sleeve to the limb. In the Office action, the Examiner has stated that the additional feature recited in claim 21 is "well known." No reference, however, is shown to disclose or suggest this feature. Accordingly, this claim, too, is believed to be allowable.

Summary

In view of the foregoing, appellant submits that the rejections of claims 1, 2, 5, 6, 8 – 13, 15 – 17, and 19 – 22 were improper, and reversal of all of the rejections is respectfully requested.

Respectfully submitted,

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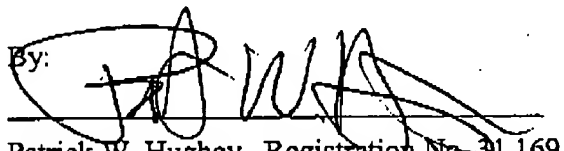
By: 

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8. Claims Appendix

1. A method for matching components of an apparatus for protecting a patient's limb from tourniquet-related injury, comprising the steps of:

selecting a tourniquet cuff component having a length sufficient for encircling a limb at a location having a limb circumference of not less than a predetermined minimum limb circumference and not more than a predetermined maximum limb circumference;

providing a limb protection sleeve component that is configured to have a tubular shape and a tubular circumference predetermined to be less than the predetermined minimum limb circumference wherein the sleeve is formed to allow elastic stretching of the tubular shape sufficient to increase the tubular circumference to be substantially equivalent to the limb circumference when the sleeve is applied to the limb between the cuff and limb, thereby applying a pressure to the limb that is greater than a predetermined minimum pressure and less than a predetermined maximum pressure; and

matching the selected tourniquet cuff component and limb protection sleeve component by marking the cuff and sleeve to indicate that those two components match one another

2. The method of claim 1 wherein the matching step comprises applying a selected color on the cuff and the same selected color on the sleeve.

5. The method described in claim 1 including the step of providing a tourniquet instrument for inflating the tourniquet cuff at a pressure sufficient to stop blood flow in the encircled limb.

6. Apparatus for protecting a patient's limb from tourniquet-related injury, comprising:

a tourniquet cuff having a length sufficient for encircling a limb having a limb circumference within a range of not less than a predetermined minimum and not more than a predetermined maximum, and wherein the cuff has a first indicium thereon that is indicative of that range;

a stretchable limb protection sleeve having a tubular shape and an unstretched circumference that is less than the predetermined minimum, wherein the sleeve is formed

to apply a pressure to the limb that is greater than a predetermined minimum pressure and less than a predetermined maximum pressure; and

matching means perceptible to a user for matching the sleeve to the first indicium of the cuff the matching means including a second indicium on the sleeve that corresponds to the first indicium on the cuff.

8. The apparatus of claim 6 wherein the sleeve is comprised of two layers, with one layer folded over another layer at a fold edge and so that the edges of the layers away from the fold edge are sewn together at a sewn edge of the sleeve.

9. The apparatus of claim 8 wherein the second indicium is incorporated into the sewn edge of the sleeve.

10. The apparatus of claim 6 wherein the cuff has a predetermined width and forms a generally cylindrical shape when encircling the limb, and whereby the sleeve is sized to be substantially wider than the cuff thereby to enable part of the sleeve to underlie the cuff around the limb while another part of the sleeve is folded over the cuff when the cuff encircles the limb.

11. The apparatus of claim 6 further comprising an instrument attached to the cuff for pressurizing the cuff.

12. The apparatus of claim 6 wherein the first indicium and the second indicium are the same color.

13. A tourniquet cuff and sleeve system comprising:

a tourniquet cuff having a width, a length, and a fastening mechanism, the cuff being flexible for being lapped upon itself into a cylindrical configuration having one of a range of circumferences and within which range the fastening mechanism completely engages to secure the cuff in the cylindrical configuration;

a tubular stretchable sleeve of uniform thickness and having an unstretched circumference that is smaller than the range of cuff circumferences, wherein the sleeve is formed to apply a pressure to a limb having a circumference within the range that is greater than a predetermined minimum pressure and less than a predetermined maximum pressure; and wherein

the sleeve has a width that is greater than the width of the cuff thereby to enable part of the sleeve to completely underlie the cuff when the cuff is in the cylindrical configuration while another part of the sleeve is folded over the cuff; and

matching means for providing a visual indication of a size correspondence between the cuff and sleeve.

15. A method for correlating one size of a number of different-sized stretchable sleeves with a particularly sized tourniquet cuff that surrounds a limb of a predetermined circumference, comprising the steps of:

selecting a sleeve that has an unstretched circumference that is smaller than the limb circumference and that applies to the limb a pressure that is greater than a first predetermined amount and less than a second predetermined amount when the sleeve surrounds the limb; and

marking the selected sleeve in a manner to show correlation with the cuff.

16. The method of claim 15 wherein the selecting step includes the step of establishing the first predetermined amount to be 2 mmHg.

17. The method of claim 15 wherein, in lieu of the marking step, the method includes the step of packaging together the correlated cuff and sleeve.

19. The method of claim 1 wherein providing the limb protection sleeve includes the step of establishing the predetermined maximum pressure applied by the sleeve to the limb to be less than a pressure for partially obstructing venous blood flow in the limb.

20. The method of claim 19 wherein the establishing step includes establishing the predetermined maximum pressure to be less than 25 mmHg.

21. The method of claim 19 wherein the step of establishing the predetermined maximum pressure applied by the sleeve to the limb includes measuring the pressure applied by the sleeve to the limb.

22. The apparatus of claim 13 wherein the circumferential length represented by the range of circumferences is greater than the width of the cuff.